



US006004972A

United States Patent [19]**Cincotta et al.**[11] **Patent Number:** **6,004,972**[45] **Date of Patent:** ***Dec. 21, 1999**[54] **THERAPEUTIC PROCESS FOR THE
TREATMENT OF THE PATHOLOGIES OF
TYPE II DIABETES**[75] Inventors: **Anthony H. Cincotta**, Andover, Mass.;
Albert H. Meier, Baton Rouge, La.[73] Assignee: **The Board of Supervisors of
Louisiana State University and
Agricultural and Mechanical College**,
Baton Rouge, La.[*] Notice: This patent is subject to a terminal dis-
claimer.[21] Appl. No.: **09/103,105**[22] Filed: **Jun. 23, 1998****Related U.S. Application Data**[63] Continuation of application No. 08/465,818, Jun. 6, 1995,
Pat. No. 5,866,584, which is a continuation of application
No. 08/158,153, Nov. 24, 1993, Pat. No. 5,468,755, which
is a continuation of application No. 07/813,135, Dec. 23,
1991, abandoned, which is a continuation-in-part of appli-
cation No. 07/463,327, Jan. 10, 1990, abandoned, which is
a continuation-in-part of application No. 07/192,332, May
10, 1988, abandoned.[51] **Int. Cl.**⁶ **A61K 31/44**[52] **U.S. Cl.** **514/288; 514/866**[58] **Field of Search** 514/288, 866[56] **References Cited****U.S. PATENT DOCUMENTS**3,074,847 1/1963 Bigsby et al. 514/271
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5,468,755 11/1995 Cincotta et al. 514/288**FOREIGN PATENT DOCUMENTS**890369 3/1982 Belgium .
3722383 1/1988 Germany .
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2192541 1/1988 United Kingdom .*Primary Examiner*—Kevin E. Weddington*Attorney, Agent, or Firm*—Darby & Darby[57] **ABSTRACT**

A process for the long term modification and regulation of lipid and carbohydrate metabolism—generally to reduce obesity, insulin resistance, and hyperinsulinemia or hyperglycemia, or both (these are the hallmarks of nonin-
sulin dependent, or Type II diabetes)—by administration (i.e., by oral, sublingual or parenteral administration) to a vertebrate, animal or human, of a dopamine agonist, e.g., bromocriptine. Administration of the bromocriptine is made over a limited period at a time of day dependent on the normal circadian rhythm of insulin resistant and insulin sensitive members of a similar species. Insulin resistance, and hyperinsulinemia and hyperglycemia, or both, can be controlled in humans on a long term basis by such treatment inasmuch as the short term daily administration resets hormonal timing in the neural centers of the brain to produce long term effects.

38 Claims, No Drawings